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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,841	11/28/2000	Kenneth H. Grabstein	2811-H	6624

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Immunex Corporation
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51 University Street
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EXAMINER

MERTZ, PREMA MARIA

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 01/08/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/724,841

Applicant(s)

Grabstein et al.

Examiner

Prema Mertz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 21, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 20-33 is/are pending in the application.
- 4a) Of the above, claim(s) 1-5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 11 6) ☐ Other:

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DETAILED ACTION

Election/Restriction

1. Applicant's election of Group II (claims 20-30) in Paper No. 10 (10/21/02) is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP.. § 818.03(a)).

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed because the claims are directed to a nucleic acid and the title recites the protein.

Appropriate correction is requested.

Claim Rejections - 35 USC § 112, first paragraph

3. Claims 20-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid consisting of at least 12 contiguous nucleotides from SEQ ID NO:1 or 4 or a nucleic acid consisting of at least 12 contiguous nucleotides of the complementary sequences of SEQ ID NO:1 or 4, does not reasonably provide enablement for a nucleic acid consisting "essentially of" at least 12 contiguous nucleotides from SEQ ID NO:1 or 4 as recited in claim 20. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

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With respect to claims 20-25, the specification does not enable a nucleic acid consisting "essentially of...". The specification does not enable the skilled artisan to make and/or use nucleic acids that "consist essentially of" as the ones disclosed (SEQ ID NO:1, 4). The issue with respect to "essentially of" is how substantial must the sequence identity be, and what portions constitute this identity? The specification does not teach which residues can be conservatively substituted without affecting the functional activity of the nucleic acid molecule. It is known to the skilled artisan that with respect to a nucleic acid molecule encoding a polypeptide, conservative amino acid substitutions outside of the active site of a protein will not affect the functional activity of the protein; however, amino acid substitutions, even conservative alterations, within the active site can inactivate the protein or change its functional activity. Absent the specific degree of sequence identity, it is unpredictable if the claimed nucleic acid molecule which "consists essentially of" the 12 contiguous nucleotides from SEQ ID NO:1 or 4 would have the desired function. Thus, without guidance as to which residues can be conservatively substituted, the skilled artisan would not be able to make and/or use the claimed nucleic acid molecule which "consists essentially of" the 12 contiguous nucleotides from SEQ ID NO:1 or 4.

Claims 26-30 are rejected under 35 USC § 112, first paragraph insofar as they depend on the above rejected claims for their limitations.

Claim Rejections - 35 USC § 112, second paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4a. Claims 20-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 20-25 recite "consisting essentially of" which is a vague and confusing term in the absence of a definition for such in the specification, because the metes and bounds of the claim are unclear. The recitation of "essentially of" at least 12 contiguous nucleotide residues is vague because this phrase encompasses any nucleic acid with a nucleotide sequence 51% identical to SEQ ID NO:1 or 4.

Claims 21 and 25 are rejected as vague and indefinite in their recitation of the limitation "about 75" nucleotides. Even though the use of the term "about" in a claim is inherently vague and indefinite, its use is appropriate when employed to limit a value which is composed of indefinitely divisible units such as inches, meters, grams, and pints, where it is impractical to produce an item which has exactly the dimension recited. Even if one could practically produce an item which is exactly 1 inch in length, the length of that item is conditional upon the temperature at which it is measured. However, when defining an invention in terms of indivisible numerical units such as the number of nucleotides in a nucleic acid, the number of amino acids in a polypeptide or the number of legs on a chair or table, the term "about" is unacceptably vague and indefinite since it is practical to employ a term which possesses the required precision. If, for example, it is Applicant's intention that the claims should encompass a nucleic acid consisting of 12 to 75 contiguous nucleotides, then

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this is exactly what the claim should recite. One would not know if the term "about 75 nucleotides" would include or exclude nucleotides 70, 65, 60, or even 80.

Claim 20 is rejected as vague and indefinite because it is unclear whether the limitation "a nucleic acid consisting of 12 contiguous nucleotides of the complementary sequence of SEQ ID NO:1 or 4" is what is included in the claim. This rejection may be obviated by deleting this limitation from claim 20 and reciting this limitation in an independent claim.

Claims 26-30 are rejected under 35 USC § 112, second paragraph insofar as they depend on the above rejected claims for their limitations.

Conclusion

No claim is allowed.

Claims 20-30 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, set forth in this Office action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 305-3014 or (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 746-5300.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express

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waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Prema Mertz
Prema Mertz Ph.D.
Primary Examiner
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December 16, 2002